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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,914	08/10/2001	Timothy P. Tully	1314.2004-001	5180

21005 7590 09/29/2005

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,914	TULLY ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 0904*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-106* is/are pending in the application.

4a) Of the above claim(s) *2,9,10,12,13,21,22,24-48,59 and 65-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,11,14-20,23,49-58,60-64 and 94-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's response filed on September 9, 2004. Claims 1-106 are pending. Claims 1, 3-8, 11, 14-20, 23, 49-58, 60-64, 94-106 are examined herein.

Response to Arguments

Applicant's arguments have been fully considered but found not persuasive. Applicants argue that none of the cited references alone in combination would have suggested the claimed invention to one of ordinary skill in the art at the time the invention was made with a reasonable expectation of success. Applicant also states that the pathway which effect CREB function would be affected by the claimed therapy was not suggested by the combination of the cited references.

However, it is well known in the art that in the treatment of stroke, rehabilitation of the individual suffering from a stroke should begin therapy as early as possible, even when the patient is on intravenous medication. The Merck Manual is cited as extrinsic evidence of the ordinary protocol in treating a stroke patient.

It is noted that the applicant argues the affect of PDI on CREB function. It is well known in Patent Law that if applicants are claiming a biological pathway as the basis for their invention then a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed

method. The patient, condition to be treated, and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompasses by the claims.

Therefore, the teachings in Takayama et al. and Katzung that phosphodiesterase inhibitors are useful in the treatment of stroke and the extrinsic teachings in Merck that it is well known in the art to treat a stroke victim early, clearly obviates applicants claims. As the claims are drafted the patient is an individual suffering from a stroke. Such a patient would be on medication as soon as possible and be given therapy as early as possible. The rejection of May 7, 2003 is deemed proper and repeated herein.

Moreover, applicant argues that Christensen IV et al. do not disclose the use of phosphodiesterase inhibitors in the treatment of rehabilitation of cognitive deficits associated with stroke. Examiner respectfully disagrees. Christensen IV et al. discloses the use of rolipram, which is a phosphodiesterase inhibitor by applicant's own admission, for the treatment of stroke. The Merck Manual discloses a training protocol for stroke victims. The motivation is clear to administer the anti-shock medication in conjunction with the training protocol since the Merck Manual states that the training protocol should be started as early as possible towards patient's rehabilitation.

In response to applicant's arguments against the references, one cannot show nonobviousness by attacking references individually where the rejections are based on the combination of references. See *In re Keller*, 642 F. 2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Finally, applicants argue that one skilled in the art would reasonably expect the instant augmented cognitive training method employing phosphodiesterase inhibitors, other than rolipram and IBMX, can be successfully used, for example, in the treatment of a cognitive deficit associated with stroke. Examiner respectfully points out that there are a multitude of phosphodiesterase inhibitors with varying structures, reactivities, and bioavailabilities., which differ from rolipram and IBMX. Relatively non-selective phosphodiesterase inhibitors include the minor stimulant caffeine and the bronchodilator theophylline. Sildenafil, Tadalafil and Vardenafil are selective inhibitors of type V phosphodiesterase (PDE5), which is cGMP-specific and responsible for the degradation of cGMP in the corpus cavernosum. Enoximone, which inhibits PDE IV, and milrinone, which inhibits PDE IIIc, are useful for short-term treatment of cardiac failure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SHENGJUN WANG
PRIMARY EXAMINER